

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Prior to the present amendment, claims 1, 2, 4, 5, 13-15, 17 and 26 were pending and under consideration. By the present amendment, claims 13-15, 17 and 26 are canceled and re-presented as new claims 32-34, 36 and 35, respectively. In addition, claims 7-9, 11 and 12, which correspond to original and previously presented claims 13-15, 17 and 18, and which were considered canceled in the present Office Action, are re-presented as new claims 27-31. These new claims correspond exactly to previously presented claims, and, therefore, do not constitute new matter. New claims 37-43 are added to more specifically recite certain aspects of the present invention. Specifically, these claims correspond to claims 1, 2, 4, 5, 30, 34 and 36, except the phrase "about" is removed when reciting numerical ranges.

Claim Objections

In the present Office Action, the Examiner notes that the original claim numbering was not preserved and objects to claims 7-9, 11-15, 17 and 26 as not currently matching the claims sets previously presented. In addition, the Examiner considered claims 6-12 and 18-25 canceled.

In a telephone interview with the Examiner conducted on May 6, 2004, Applicants' representative explained that the inconsistent claim numbering was an inadvertent error resulting from automated formatting, and the Examiner advised that the affected claims be canceled and re-presented as new claims. Following the Examiner's suggestion, pending claims 13-15, 17 and 26 are canceled and re-presented as new claims 32-34, 36 and 35, respectively. In addition, claims 7-9, 11 and 12, which correspond to original and previously presented claims 13-15, 17 and 18, and which were canceled absent Applicants' intent, are re-presented as new claims 27-31. The present claims now conform to the claims under prosecution prior to the inadvertent numbering error of the previously submitted amendment. No claims directed to additional subject matter have been added.

In the Advisory Action mailed September 22, 2004, the Examiner indicated that the non-entered Amendment submitted on June 21, 2004, was insufficient to place the application in condition for allowance, asserting that new claims 27-43 do not appear to further limit claims from which they depend, or appear to duplicate already claimed subject matter.

Applicants respectfully disagree with this conclusion, and submit that claims 27-43 are drawn to specific aspects of the present invention, which are distinct from those of the other claims remaining in the application upon entry of the present amendment, which includes the cancellation of claims 13-15, 17 and 26. Applicants further submit that claims 27-35 are directed to a method of treating solid tumors, whereas the other remaining pending claims are all directed to liposomal unit dosage forms. Furthermore, claims 36-43 represent distinct subject matter from the other remaining pending claims, since the phrase "about" is removed from these claims when reciting numerical ranges, as opposed to the other claims, *i.e.*, claims 1, 2, 4, 5, 30, 34, and 36.

Applicants respectfully submit that the objection to claims 7-9, 11-15, 17 and 26 has been overcome by their cancellation and re-presentation as new claims, which are drawn to distinct aspects of the invention as compared to the other claims remaining pending upon entry of the present amendment. Accordingly, Applicants request that this basis of objection be withdrawn.

Withdrawal of Rejections Under 35 U.S.C. §§ 102(b) and 103(a)

Applicants wish to thank the Examiner for his withdrawal of all prior-art based rejections to pending claims, in light of the amendments and remarks provided in the amendment filed February 19, 2004.

Specifically, Applicants acknowledge the Examiner's withdrawal of the rejection under 35 U.S.C. § 102(b) of claims 6 and 7 and the rejection under 35 U.S.C. § 103(a) of claims 8, 10 and 11, as unpatentable over Madden *et al.* in view of Slater *et al.*, in light of their cancellation. Applicants note that these claims are not presented as new claims in the present amendment. Accordingly, Applicants submit that this basis of rejection has been overcome in regard to all claims.

Applicants thank the Examiner for his withdrawal of the rejection under 35 U.S.C. § 103(a) of claims 1, 2, 4, 5 and 23, as unpatentable over Madden *et al.*, in light of the remarks provided in the amendment filed February 19, 2004. Applicants note that claim 23, which was inadvertently numbered claim 17 in the previous amendment, is canceled and re-presented as new claim 36 in the present amendment. Accordingly, Applicants submit that this basis of rejection has been overcome in regard to all claims.

Finally, Applicants thank the Examiner for his withdrawal of the rejection under 35 U.S.C. § 103(a) of claims 1, 2, 4, 5, 13-15, 17 and 26, as unpatentable over Madden *et al.* in view of Ormrod *et al.*, in light of the remarks provided in the amendment filed February 19, 2004. Applicants note that claims 13-15, and 17, which were inadvertently numbered claims 7-9, and 11 in the previous amendment, are canceled and re-presented as new claims 27-30 in the present amendment. Claim 26 is also canceled and re-presented as new claim 35.

Applicants note that the Examiner did not explicitly withdraw this basis of rejection as to previous claims 18-21 and 23 (currently re-presented as claims 31-34 and 36), since he deemed them canceled by the previous amendment. However, Applicants submit that claims 31-34 (originally claims 18-21 and inadvertently numbered as claims 12-15 in the previous amendment) are also clearly non-obvious in light of this combination of references, since they depend from and include additional limitations as compared to claim 30. In addition, Applicants submit that claim 36 (originally claim 23 and inadvertently numbered as claim 17 in the previous amendment) is also non-obvious in light of these references, for the same reasons as found persuasive for related claims, including, *e.g.*, claim 1. Specifically, neither Madden *et al.* nor Ormrod *et al.* teach or suggest the use of liposomal camptothecins within the claimed dosages nor recognize that the claimed liposomal camptothecin formulations demonstrate increased efficacy at equivalent dosages and are efficacious at lower dosages than previously described liposomal camptothecin formulations, as detailed in the previously submitted Declaration of Sean Semple, M.Sc.. Accordingly, these references, either alone or in combination, fail to teach each element of the claimed invention and, furthermore, would not motivate the skilled artisan to utilize such lower dosages. Accordingly, Applicants respectfully

request that the Examiner now consider and withdraw this basis of rejection as regard to claims 31-34 and 36.

Double-Patenting Rejection

Claims 1, 2, 4, 5, and 17 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-35, 37, 39-57 and 60-63 of copending Application No. 09/896,812. Specifically, the Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct because they are both drawn to liposomal formulations comprising camptothecin and/or topotecan compounds. In addition, in the Advisory Action mailed September 22, 2004, the Examiner asserts that the recitation of specific unit dosage forms in the present invention is insufficient to overcome the provisional obviousness-type double patenting rejection, since the selection of appropriate dosages requires no more than routine skill in the art.

Applicants respectfully traverse this basis of rejection and submit that the claimed invention is not obvious in light of the claims of copending Application No. 09/896,812. The claims of the instant application are drawn to liposomal topotecan unit dosage forms, said unit dosage form comprising specific dosages, including, *e.g.*, dosages of from about 0.01 mg/M²/dose to about 7.5 mg/M²/dose. The identified claims of copending Application No. 09/896,812 clearly do not recite specific unit dosages of liposomal topotecan and, therefore, cannot render the instant claims obvious.

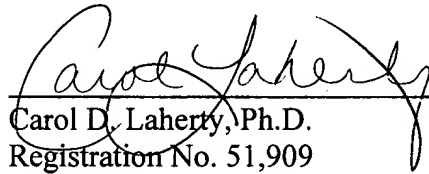
Furthermore, Applicants note that the ranges of dosages recited in the instant application are lower than liposomal topotecan dosages previously described as being efficacious in the art. Accordingly, even if the selection of appropriate dosages normally requires no more than routine experimentation by one of skill in the art, such is not the case in the present situation, where the invention provides improvements that allow the use of a lower dosage than previously shown to be efficacious in the art (*see, e.g.*, Declaration of Sean Semple, submitted October 7, 2003, which details advantages of the present invention over the prior art, including increased efficacy which permits the use of lower dosages). Accordingly, in the present situation, it is only the teachings of the instant application that suggest that the claimed dosages

could be used. Absent these teachings, a skilled artisan would have no motivation to test or select a dosage within the claimed ranges, since the prior art clearly established that higher dosages were required for efficacy. Therefore, Applicants submit that the instant claims are directed to patentably distinct subject matter and respectfully request that the provisional double patenting rejection be withdrawn.

Applicants respectfully submit that all of the claims remaining in the application are now clearly allowable. In light of the confusion created by the previous misnumbering of certain claims, Applicants request that the Examiner contact the undersigned attorney to clarify any remaining issues. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC


Carol D. Laherty, Ph.D.
Registration No. 51,909

CDL:teb

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

533062_1.DOC